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10/598,604	09/05/2006	Shigeru Ashida	JCLA16171	7700
23900	7590	03/15/2010		
J C PATENTS 4 VENTURE, SUITE 250 IRVINE, CA 92618			EXAMINER GWARTNEY, ELIZABETH A	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,604	Applicant(s) ASHIDA ET AL.	
	Examiner Elizabeth Gwartney	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Amendment filed November 16, 2009 has been entered. Claim 8 has been added.

Claims 1, 4 and 6-8 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 8 recites "which contains no water-insoluble calcium species." Note, negative limitations in a claim which do not appear in the specification as filed introduce new concepts and violate the description requirement of 35 USC 112, first paragraph, *Ex Parte Grasselli, Suresh, and Miller*, 231 USPQ 393, 394 (Bd. Pat. App. and Inter. 1983); 783 F. 2d 453. Here, the specification states that "the stability can be maintained even when water-soluble minerals, not to mention water-insoluble minerals, are added." Further, the specification states that "the present food or drink is not exclusive of containing water-insoluble minerals." Clearly, the negative limitation in claim 8 does not appear in the specification as filed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (EP 1 364 585 A1) in view of Calapini et al. (US 2004/0101597).

Regarding claim 1, Saito et al. disclose an acidic beverage comprising acid-soluble soybean protein and calcium chloride dihydrate and has a pH value of 3.8 (Abstract, p.

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7/Example 3/[0041], p.12/Example 10/[0065]). Given that Saito et al. disclose one or minerals including calcium chloride dehydrate it is clear that the mineral is intrinsically water soluble.

While there is no explicit disclosure regarding the preparation of an acid soybean beverage using powder obtained in Example 3 by the addition of calcium chloride dihydrate, given the Saito et al. disclose the equivalence and interchangeability of the protein powders made by examples 1–5 (p.8/Table 1) it would have been obvious to one of ordinary skill in the art to use the powder of example 3 in the beverage of example 10.

While Saito et al. disclose calcium chloride dihydrate, the reference does not explicitly disclose that the recited water-soluble mineral is added after the preparation of the soybean protein in the amount of 100-250 mg per 100 g of the acidic food or drink.

Calapini et al. teach an acidic beverage fortified with 240-275 mg/200 ml drink calcium including in-situ formed calcium citrate, calcium malate or calcium citrate malate and further including calcium chloride and calcium lactate gluconate (Abstract, [0012], p. 3-5/Experiments 1-7). Calapini et al. teach that calcium is an essential nutrient for healthy bone and teeth development and a diet deficient in calcium is thought to be a factor in the development of osteoporosis ([0004]). Calapini et al. also teach that since the body does not produce calcium, the body requires an external supply of calcium ([0005]).

Saito et al. and Calapini et al. are combinable because they are concerned with the same field of endeavor, namely, acidic beverages. It would have been obvious to one of ordinary skill in the art at the time of the invention to have added water-soluble calcium salts, as taught by Calapini et al. to the acidic beverage of Saito et al. for the purpose of making a calcium fortified

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beverage for consumption since calcium is an essential nutrient for healthy bone and teeth development.

Given Calapini et al. disclose calcium salts which exhibit water solubility, intrinsically the salt combination would not contain water-insoluble calcium species.

Regarding the method limitations recited in claim 1, note that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself (i.e. acid-soluble soybean protein). *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.). In this case, absent evidence to the contrary, the acidic drink of the present invention is the same as the acidic beverage disclosed by modified Saito et al. comprising an acid-soluble soybean protein as presently claimed.

Regarding claim 4, modified Saito et al. disclose all of the claim limitations as set forth above and that the aqueous solution of the acid-soluble soybean protein has a pH of 3.5 (i.e. acidic pH - [0041]).

Regarding claim 6, modified Saito et al. disclose all of the claim limitations as set forth above that no stabilizer is used ([0065]/Example 10). Further, Saito et al. disclose a food or drink which is produced without a homogenizing step (see Example 10 wherein no homogenization step is disclosed - [0065]).

Regarding claim 7, modified Saito et al. disclose all of the claim limitations as set forth above. Further, Saito et al. disclose wherein the acidic food is a jelly beverage, i.e. thick fluid food ([0066]).

Response to Arguments

8. Applicant's arguments filed November 16, 2009 have been fully considered but they are not persuasive.

Applicants note that Calapini et al. teach an acidic beverage containing calcium in an amount in the range of 240-275 mg/200ml (p. 3-5/Experiments 1-7) and not in the range of 240-275 mg/100ml as indicated in the Non-Final Office Action. Further, applicants find that Calapini et al. teach calcium fortification wherein about 30% to about 60% of the total calcium is from the *in-situ* formed calcium citrate, calcium malate or calcium citrate malate which are all water-insoluble calcium salts. Therefore, applicants argue that the water-soluble calcium in Calapini et al. is about 84-96 mg/100ml which does not overlap with the claimed range of 100-250 mg/100 g.

While it is noted that Calapini et al. teach an acidic beverage containing calcium in an amount in the range of 240-275 mg/200ml, it is the Examiner's position that Calapini et al. still teach water-soluble calcium in the range of 120-137.5 mg/100 ml which overlaps with the claimed range of 100-250 mg/100 g (wherein the density of the beverage is approximately 1 g/ml). Further, while calcium citrate and calcium citrate malate are less soluble in water than calcium salts such as calcium lactate, calcium malate or calcium gluconate, each exhibit a significant degree of solubility in water. In this case, claim 1 requires one or more water-soluble

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minerals in an amount of 100-250 mg per 100 g of acidic food or drink. There is nothing in the claim that limits the degree of solubility. In fact, the specification of the present invention provides that calcium minerals with solubility above 10 mg are suitable and include the disclosed calcium salts as minerals used in the present invention (*see* p.8/Table 1).

Applicants argue that it is non-obvious to combine Calapini et al. with Saito et al. First, applicants find that Calapini et al. "is intended to be applied to drinkable liquids in citric acid and/or malic acid that easily form precipitate with calcium ions but does not concerned with the precipitate issue of soybean protein in presence of calcium ions at all." Applicants assert that there would have been on need to apply the "*in-situ formation*" technique of Calapini et al. to the acidic protein foods of Saito et al. "to increase the calcium content without causing undesirable taste due to precipitates."

It is not suggested that Calapini et al. teach an acidic protein food. Here Calapini et al. is used to teach calcium fortification of acidic beverages and the health benefits of calcium consumption. Given Saito et al. teach an acidic food or beverage, since Calapini et al. teach fortifying acidic beverages with a combination of calcium salts, it would have been obvious to one of ordinary skill in the art to have applied teachings of Calapini et al. to fortify the acidic protein beverage of Saito et al. to make a more healthful beverage.

Second, applicants explain that the in-situ formed calcium citrate, calcium malate or calcium citrate malate of Calapini et al. is in a metastable state and easily precipitates to the low equilibrium solubility as being disturbed by, for example raised temperature. Since the soybean protein of Saito et al. inevitably interacts with calcium ions, applicants argue that it is quite difficult to predict whether a high concentration of *in-situ* formed calcium citrate, calcium malate

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or calcium citrate malate could be achieved if the “*in-situ formation*” of Calapini et al. were applied to the acidic protein foods of Saito et al.

Given modified Saito et al. disclose an acidic food composition substantially similar to that presently claimed, it is clear that a high concentration of calcium salts, as taught by Calapini et al. could be achieved.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794